UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

**OFFICE OFCHEMICAL SAFETY
AND POLLUTION PREVENTION**

MEMORANDUM

Date: 14-April-2011

Subject: **Tetraconazole.** Acute, Chronic, and Cancer Dietary Exposure and Risk Assessment for Application of Tetraconazole to Field Corn, Popcorn, Small Fruit Vine-climbing (except fuzzy kiwifruit) Subgroup 13-07F, and Low-Growing Berry (except cranberry) Subgroup13-07G.

PC Code: 120603	**DP Barcode:** D381912
Decision No.: 435873	**Registration No.:** none
Petition No.: 0E7735	**Regulatory Action:** Section 3
Risk Assessment Type: Dietary	**Case No.:** 7043
TXR No.: not applicable	**CAS No.:** 112281-77-3
MRID No: none	**40 CFR:** 180.557

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Executive Summary

The residues of concern in plants and livestock following application of tetraconazole includes compounds which HED has determined to be toxicologically different from tetraconazole. The current memorandum pertains only to dietary exposure to tetraconazole and those compounds which HED has determined are toxicologically equivalent to tetraconazole. Information concerning exposure to the remaining residues of concern can be found in the HED risk assessment D380618 (A. Nowotarski *et al.*, in draft).

Acute, chronic, and cancer dietary risk assessments were conducted using the Dietary Exposure Evaluation Model - Food Consumption Intake Database (DEEM-FCID™, ver. 2.03) which incorporates the food consumption data from the United States Department of Agriculture (USDA) Continuing Surveys of Food Intakes by Individuals (CSFII; 1994-1996 and 1998). These analyses were conducted in support of the proposed application of tetraconazole to field corn, popcorn, small fruit vine-climbing (except fuzzy kiwifruit) subgroup 13-07F, and low-growing berry (except

cranberry) subgroup13-07G. The following paragraphs are summaries of the acute, chronic, and cancer dietary exposure analyses resulting from the proposed/registered crops.

Acute: The unrefined acute analysis resulted in exposure estimates less than HED's level of concern (≤1.8% acute population adjusted dose (aPAD); children 1-2 years old were the most highly exposed population subgroup).

Chronic: The chronic analysis (food and water) was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies, and projected percent crop treated estimates. The resulting exposure estimates are less than HED's level of concern (all exposures were ≤5% cPAD; all infants <1 year old were the most highly exposed population subgroup).

Cancer: The cancer analysis (food and water) was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies, and projected percent crop treated estimates. The resulting exposures estimates yielded a cancer risk for the U.S. population of 3×10^{-6} which is less than HED's level of concern. A critical commodity analysis for the cancer run (U.S. population) indicated that the major contributors were water (63% of total exposure), strawberry (11% of total exposure), dairy products (5% of total exposure), and soybean oil (4% of total exposure).

I. Introduction

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which HED has concluded will result in no unreasonable adverse health effects). This dose is referred to as the PAD. The PAD is equivalent to the point of departure divided by the required uncertainty and/or safety factors. For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. HED is generally concerned when estimated cancer risk exceeds one in one million. References which discuss the acute and chronic risk assessments in more detail are available on the EPA/pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf; or see SOP 99.6 (20-Aug-1999). The most recent dietary risk assessment for tetraconazole was conducted by T. Bloem (D353708, 26-Jun-2008).

II. Residue Information

Residues of Concern in Plants and Livestock: Table 1 is a summary of the residues of concern in plants and livestock (for a complete discussion concerning these conclusions, refer to D321751, M. Clock-Rust *et al.*, 26-Jan-2007). HED concluded that the toxicological effects resulting from exposure to 1,2,4-triazole (T), triazolyl alanine (TA), triazolyl acetic acid (TAA), triazolyl hydroxypropionic acid (THP), and all labile conjugates of these compounds and M14360(C-1)-alcohol are different from that resulting from exposure to tetraconazole; HED concluded that the toxicity of the remaining metabolites is identical to that of tetraconazole. The current dietary exposure analysis pertains only to exposure to those compounds which HED has concluded are toxicologically similar to tetraconazole (i.e. tetraconazole, M14360-alcohol (free and conjugated), M14360-acid, M14360-DFA, and M14360-hydroxydetriazolyl-*O*-malonyldiglucoside). Information concerning exposure to the remaining residues of concern can be found in the HED risk assessment document D380618 (A. Nowotarski *et al.*, in draft).

Table 1: Residues for Tolerance Expression and Risk Assessment.

Matrix	Residues included in Risk Assessment	Residues included in Tolerance Expression
Shelled Pea and Bean	tetraconazole and 1,2,4-triazole (T), triazolyl alanine (TA), triazolyl acetic acid (TAA), and all labile conjugates of these compounds	Tetraconazole
Remaining Plants	tetraconazole, M14360-alcohol (free and conjugated), M14360-acid, M14360-DFA, M14360-hydroxydetriazolyl-O-malonyldiglucoside, and T, TA, TAA and all labile conjugates of these compounds	Tetraconazole
Livestock	tetraconazole, M14360-alcohol (free and conjugated), M14360-acid, M14360-DFA, M14360(C-1)-alcohol (free and conjugated), M14360-hydroxydetriazolyl-*O*-malonyldiglucoside, and T, TA, THP, and TAA and all labile conjugates of these compounds	Tetraconazole
Rotational Crops	tetraconazole, M14360-acid, M14360-DFA, M14360(C-1)-alcohol (free and conjugated), and TA, THP, and TAA and all labile conjugates of these compounds	Tetraconazole
Drinking Water	tetraconazole	not applicable

Currently Established Tolerances and HED-Recommended Tolerances: Tetraconazole is currently registered for application to sugar beet, grape, peanut, pecan, and soybean with tolerances ranging from 0.063-1.0 ppm (40 CFR 180.557). Tolerances as a result of secondary residues are also established in/on poultry and ruminant commodities (0.01-0.25 ppm). The petitioners are currently requesting registration for application of tetraconazole to field corn, popcorn, small fruit vine-climbing (except fuzzy kiwifruit) subgroup 13-07F, and low-growing berry (except cranberry) subgroup13-07G. HED has reviewed the data submitted in support of these petitions and is recommending for establishment of the following tolerances for residues of tetraconazole (D382300, T. Bloem, 14-Apr-2011): small fruit vine-climbing (except fuzzy kiwifruit) subgroup 13-07F - 0.20 ppm; low-growing berry subgroup 13-07G (except cranberry) - 0.25 ppm; field/pop corn grain - 0.01 ppm; field corn forage - 1.1 ppm; field/pop corn stover - 1.7 ppm; milk - 0.03 ppm; milk fat - 0.75 ppm; fat (cattle, goat, horse, sheep) - 0.15 ppm; liver (cattle, goat, horse, sheep) - 1.50 ppm; meat byproducts (cattle, goat, horse, sheep) - 0.15 ppm; and poultry meat byproducts - 0.05 ppm.

Residue Estimates for the Acute and Chronic Analyses: The following text are summaries of the residue estimates incorporated into the acute, chronic, and cancer analyses for primary crops, rotational crops, and livestock.

Primary Crops: The available field trial and processing studies monitored for residues of tetraconazole *per se*. These data are sufficient for soybean tetraconazole risk assessment; however, the residues of concern for a tetraconazole risk assessment in the remaining proposed/registered crops includes tetraconazole, M14360-alcohol (free and conjugated), M14360-acid, M14360-DFA, and M14360-hydroxydetriazolyl-O-malonyldiglucoside. The magnitude of these residues were estimated based on the tetraconazole metabolites to tetraconazole residues ratios from the sugar beet, grape, and wheat metabolism studies. Based on these metabolism data, HED employed the following residue ratios for estimation of the metabolite residues in the proposed/registered crops: sugar beet root ratio of 0.26x for sugar beet, peanut, and pecan; sugar beet leaves residue ratio of 0.33x for grape, subgroup 13-07F, and subgroup 13-07G (grape metabolism studies only included parent as a reference standard with none of the metabolites identified; therefore, a ratio could not be calculated); wheat straw residue ratio of 0.02x for field/pop corn (no metabolites were identified in wheat grain). Table 2 is a summary of the tetraconazole *per se* residues and estimated combined residues of concern in the primary plant commodities for both acute and chronic analyses.

Rotational Crops: Based on the field rotational crop data (D382300, T. Bloem, 14-Apr-2011), the proposed/registered application rates and plantback intervals, and the parent to metabolite residue ratios from the confined rotational crop study of ≥0.7x, HED concludes that the combined residues of tetraconazole, M14360-acid, and M14360-DFA will be insignificant in/on rotational crops.

Livestock: The livestock tolerances are based on residues of tetraconazole *per se* derived from the consumption of feed commodities which contain residues of tetraconazole *per se*; however, as stated above, the residues of concern for a tetraconazole risk assessment in both feed (excluding soybean feed commodities) and livestock commodities are tetraconazole, M14360-alcohol (free and conjugated), M14360-acid, M14360-DFA, and M14360-hydroxydetriazolyl-O-malonyldiglucoside. Therefore, the acute and chronic dietary assessment included livestock residues which were calculated based on dietary burdens which included all of the residues of concern for a tetraconazole risk assessment. This dietary burden was then used to calculate anticipated residues in the livestock tissues based on the tetraconazole *per se* transfer coefficients (i.e., assessments assume that transfer coefficients for the tetraconazole metabolites are identical to tetraconazole). Table 3 is a summary of the dietary burden calculations and Table 4 is a summary of the residue estimates in the livestock commodities for both the acute and chronic analyses. HED notes the following: **(1)** the livestock feeding studies (ruminant and poultry) employed a minimum of three animals per dosing level with the highest and average residue at each dosing level used for calculation of the acute and chronic transfer coefficients, respectively; **(2)** if the acute residue estimates for the livestock commodities in Table 4 were less than the tolerance, then tolerance-level residues were assumed; **(3)** the dairy cattle dietary burden was used for estimation of residues in cattle tissue; **(4)** due to the high residue in ruminant/hog liver as compared to the other tissue residues, HED concluded that residues in ruminant/hog meat byproducts will be based on the residue in fat (next highest after liver); and **(5)** the peanut and soybean application scenarios prohibit the feeding of hay and/or forage to livestock.

Percent Crop Treated: The acute analysis assumed 100% crop treated and the chronic and cancer analyses incorporated the following projected percent crop treated estimates (see attachments 1 and 2): sugar beet - 70% (attachment 2); peanut - 77% (attachment 2); field corn - 9% (attachment 1); and soybean - 5% (attachment 1; attachment 2 also contains a percent crop treated estimate for soybean but this was revised in attachment 1).

Table 2: Food/Feed Residue Estimates for Acute, Chronic, and Cancer Analyses.						
Matrix	tetraconazole residue (ppm)		Comment	factor[1]	total residue[2]	
	acute	chronic/ cancer			acute	chronic/ cancer
soybean (seed, hulls, and meal)	0.15	0.046	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (46614332.der.doc) multiplied by 2x to account for insufficient analytical method (D349705, T. Bloem, 2-Apr-2008)	--[3]	0.15	0.046
soybean oil	0.80	0.212	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (46614332.der.doc) multiplied by 2x to account for insufficient analytical method (D349705, T. Bloem, 2-Apr-2008) multiplied by the average processing factor (4.6x; 46614320.der.doc)	--[3]	0.80	0.212
sugar beet root sugar	0.12	0.004	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue multiplied by 0.1x processing factor (D254411, W. Donovan, 18-May-2000, D342523, T. Bloem, 22-Aug-2007)	0.26	0.15	0.005
sugar beet molasses	0.25	0.112	**acute** tetraconazole residues = tolerance residue **chronic** tetraconazole residues = average field trial residue multiplied by 2.8x processing factor (D254411, W. Donovan, 18-May-2000, D342523, T. Bloem, 22-Aug-2007)	0.26	0.315	0.141
sugar beet dried pulp	0.20	0.084	**acute** tetraconazole residues = tolerance residue **chronic** tetraconazole residues = average field trial residue multiplied by 2.1x processing factor (D254411, W. Donovan, 18-May-2000, D342523, T. Bloem, 22-Aug-2007)	0.26	0.252	0.106
peanut (nutmeat and meal)	0.03	0.013	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (D259231, W. Donovan, 18-May-2000)	0.26	0.038	0.016
peanut oil	0.10	0.043	**acute** tetraconazole residues = tolerance residue **chronic** tetraconazole residues = average field trial residue multiplied by 3.34x processing factor (D259231, W. Donovan, 18-May-2000)	0.26	0.126	0.054
Pecan	0.04	0.007	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (46037601.der.doc)	0.26	0.050	0.009
grape juice	0.20	0.00186	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue multiplied by 0.06x processing factor (47270101.der.doc; 47435201.der.doc)	0.33	0.266	0.002
Raisin	0.20	0.0282	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue multiplied by 0.91x processing factor (47270101.der.doc; 47435201.der.doc)	0.33	0.266	0.038
subgroup 13-07F	0.20	0.031	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (47270101.der.doc)	0.33	0.266	0.041
subgroup 13-07G	0.25	0.091	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (48131301.der.docx)	0.33	0.332	0.121
field/pop corn grain	0.01	0.005	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues =1/2 LOQ; all residues were LOQ including those from 5x rate (48135102.der.docx)	0.02	0.010	0.005
field corn forage	1.1	0.401	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (48135102.der.docx)	0.02	1.122	0.409
field/pop corn stover	1.7	0.453	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (48135102.der.docx)	0.02	1.734	0.462

Table 2: Food/Feed Residue Estimates for Acute, Chronic, and Cancer Analyses.						
Matrix	tetraconazole residue (ppm)		Comment	factor[1]	total residue[2]	
aspirated grain fractions	1.0	0.345	**acute** tetraconazole residue = tolerance residue **chronic** tetraconazole residues = average field trial residue (46614332.der.doc) multiplied by 2x to account for insufficient analytical method (D349705, T. Bloem, 2-Apr-2008) multiplied by the average processing factor (7.5x; 46614320.der.doc)	0.02	1.02	0.352

1 factor = residue ratios from the metabolism studies.
2 total residue = residue + (residue)(factor).
3 the non-free triazole tetraconazole metabolites are not residues of concern in soybean seed.

Table 3: Livestock Dietary Burden Calculations for Refinement of the Chronic Dietary Analysis.							
commodity[1]	Avg % Crop Treated	% diet[1]	% dry matter	residue (ppm)		dietary burden[2]	
				acute	chronic	acute	Chronic
beef cattle							
field corn forage (R)	9	15	40	1.122	0.409	0.421	0.014
sugar beet molasses (CC)	70	10	75	0.315	0.141	0.042	0.013
aspirated grain fractions (CC)	9	5	85	1.020	0.352	0.060	0.002
field corn grain (CC)	9	65	88	0.010	0.005	0.008	0.0003
soybean seed (PC)	5	5	89	0.150	0.046	0.008	0.0001
Total		**100**	**--**	**--**	**--**	**0.539**	**0.030**
dairy cattle							
field corn forage (R)	9	45	40	1.122	0.409	1.262	0.041
sugar beet molasses (CC)	70	10	75	0.315	0.141	0.042	0.013
field corn grain (CC)	9	35	88	0.010	0.005	0.004	0.0002
peanut meal (PC)	100	10	85	--	0.016	--	0.002
soybean seed (PC)	100	10	89	0.15	--	0.017	--
Total		**100**	**--**	**--**	**--**	**1.325**	**0.056**
poultry							
field corn grain (CC)	9	75	--	0.010	0.005	0.008	0.0003
peanut meal (PC)	100	25	--	--	0.016	--	0.004
soybean, meal (PC)	100	25	--	0.15	--	0.038	--
Total		**100**	**--**	**--**	**--**	**0.046**	**0.004**
hog							
Field corn grain (CC)	9	85	--	0.010	0.005	0.009	0.0004
peanut meal (PC)	100	15	--	--	0.016	--	0.002
soybean seed (PC)	100	15	--	0.15	--	0.022	--
Total		**100**	**--**	**--**	**--**	**0.031**	**0.002**

1 R = roughage, CC = carbohydrate concentrate, PC = protein concentrate; label prohibits feeding peanut hay and soybean forage/hay to livestock; percentage refers percent crop treated (see attachments 1 and 2) which were used in the chronic dietary burden calculations.
2 beef/dairy cattle dietary burden = residue x % diet ÷ % dry matter; poultry/hog dietary burden = residue x % diet; chronic calculations included the percent crop treated estimates.

Table 4: Livestock Residues for Acute and Chronic Analysis.

matrix	tetraconazole residue from feeding study[1] (ppm)			tetraconazole transfer coeffcients[2]			residue estimates[3]	
	low dosing level	middle dosing level	high ppm dosing level	low dosing level	middle dosing level	high dosing level	acute	chronic
dairy cattle								
milk[4]	<0.003	max = 0.016; avg = 0.007	max = 0.048 avg = 0.019	--	based on max res - 0.016 based on avg res - 0.007	based on max res - 0.014 based on avg res - 0.006	**0.021**	0.0004
milk fat	milk fat was not analyzed in the feeding studies; since residues in fat were significantly higher than those in muscle, HED concluded that a 25x concentration factor for milk fat was appropriate (milk fat residue = milk residue x 25)						**0.525**	0.010
skimmed milk	<0.003	<0.003	max = 0.003 avg = 0.003	--	--	based on max res - 0.0009 based on avg res - 0.0009	**0.001**	0.00005
cream	max = 0.023 avg = 0.020	max = 0.125 avg = 0.073	max = 0.391 avg = 0.283	based on max res - 0.068 based on avg res - 0.060	based on max res - 0.122 based on avg res - 0.072	based on max res - 0.115 based on avg res - 0.083	**0.162**	0.005
beef cattle/hog								
subcutaneous fat	max = 0.003 avg = 0.003	max = 0.033 avg = 0.029	max = 0.205 avg = 0.109	--	based on max res - 0.032 based on avg res - 0.029	based on max res - 0.060 based on avg res - 0.032	**beef = 0.080** **hog = 0.002**	beef = 0.002 hog = 0.00006
peritoneal fat	max = 0.029 avg = 0.016	max = 0.069 avg = 0.051	max = 0.199 avg = 0.114	based on max res - 0.085 based on avg res - 0.046	based on max res - 0.068 based on avg res - 0.050	based on max res - 0.059 based on avg res - 0.033	**beef = 0.113** **hog = 0.003**	beef = 0.003 hog = 0.0001
kidney	max = 0.007 avg = 0.005	max = 0.039 avg = 0.024	max = 0.067 avg = 0.055	based on max res - 0.021 based on avg res - 0.016	based on max res - 0.038 based on avg res - 0.024	based on max res - 0.020 based on avg res - 0.016	**beef = 0.050** **hog = 0.001**	beef = 0.001 hog = 0.00005
liver	max = 0.371 avg = 0.268	max = 0.662 avg = 0.376	max = 1.636 avg = 1.345	based on max res - 1.091 based on avg res - 0.789	based on max res - 0.649 based on avg res - 0.368	based on max res - 0.481 based on avg res - 0.395	**beef = 1.446** **hog = 0.034**	beef = 0.044 hog = 0.002
muscle	<0.003	max = 0.006 avg = 0.005	max = 0.015 avg = 0.011	--	based on max res - 0.006 based on avg res - 0.005	based on max res - 0.004 based on avg res - 0.003	**beef = 0.008** **hog = 0.0002**	beef = 0.0003 hog = 0.00001
poultry								
liver	max = 0.011 avg = 0.010	max = 0.029 avg = 0.026	max = 0.081 avg = 0.073	based on max res - 0.159 based on avg res - 0.145	based on max res - 0.120 based on avg res - 0.108	based on max res - 0.113 based on avg res - 0.102	**0.0073**	0.0006
kidney	<0.01	<0.01	max = 0.049 avg = 0.040	--	--	based on max res - 0.069 based on avg res - 0.056	**0.0032**	0.0002
skeletal muscle	<0.01	<0.01	max = 0.021 avg = 0.021	--	--	based on max res - 0.029 based on avg res - 0.029	**0.0013**	0.0001
abdominal fat	max = 0.045 avg = 0.038	max = 0.140 avg = 0.115	max = 0.456 avg = 0.387	based on max res - 0.652 based on avg res - 0.551	based on max res - 0.581 based on avg res - 0.477	based on max res - 0.639 based on avg res - 0.542	**0.030**	0.002
skin and subcutaneous fat	max = 0.019 avg = 0.015	max = 0.044 avg = 0.041	max = 0.181 avg = 0.164	based on max res - 0.275 based on avg res - 0.217	based on max res - 0.183 based on avg res - 0.170	based on max res - 0.253 based on avg res - 0.230	**0.013**	0.001
eggs[5]	max = 0.011 avg = 0.008	max = 0.034 avg = 0.025	max = 0.135 avg = 0.089	based on max res - 0.159 based on avg res - 0.116	based on max res - 0.141 based on avg res - 0.104	based on max res - 0.189 based on avg res - 0.125	**0.0087**	0.0005

1 ruminant feeding study - D254411, W. Donovan, 18 May-2000 (dietary burdens of 0.34 ppm, 1.02 ppm, and 3.4 ppm); poultry feeding study - 46614307.der.wpd (dietary burdens of 0.069 ppm, 0.241 ppm, and 0.714 ppm); the livestock feeding studies (ruminant and poultry) employed a minimum of three animals per dosing level with the highest and average residue at each dosing level used for calculation of the acute and chronic transfer coefficients, respectively.

2 transfer coefficient = tetraconazole residues ÷ dietary burden.

3 residue estimate = dietary burden x transfer coefficient; the highest transfer coefficient derived from a dosing level which resulted in quantifiable residues was used; for the acute analysis the residues in bold were < tolerance therefore tolerance was used.

4 residues in milk peaked on the third day of dosing; therefore, the average residue is for all samples collected on day 3 and after.

5 residues in egg peaked on the tenth day of dosing; therefore, the average residue is for all samples collected on day 10 and after.

III. Drinking Water Data

EFED provided modeled ground water (Screening Concentration In Ground Water (SCIGROW); ver. 2.3) and surface water (Pesticide Root Zone Model (PRZM ver. 3.12.2) and Exposure Analysis Modeling System (EXAMS ver. 2.98.04.06)) estimated drinking water concentrations (EDWCs) for tetraconazole *per se* resulting from the proposed application scenarios (EFED memorandum - D380619, C. Koper, 12-Oct-2010); however, previously provided PRZM/EXAMS EDWCs were greater and were therefore incorporated in the current dietary analyses (see bolded numbers in Table 5; these represent the highest EDWCs for the proposed/registered crops). For derivation of the incorporated EDWCs, see EFED memorandum D347805 (I. Maher, 1-Jul-2008). The water estimates were incorporated directly into the dietary exposure analysis via the water sources direct (all sources) and indirect (all sources) commodities. The water models and their description are available at the EPA internet site: http://www.epa.gov/oppefed1/models/water/.

Table 5: Summary of Modeled Water Estimates.

Scenario	Tetraconazole per se concentration (µg/L; ppb)		
	Peak	Yearly	30-Year-Annual Average
Minnesota - sugar beets aerial spray[1]	6.68	**4.68**	**3.29**
Georgia - pecans aerial spray[2]	**10.45**	3.48	2.84

[1] EDWCs assumed 0.87 of the basin cropped (assumes 100% of the crop treated).
[2] EDWCs assumed 0.85 to account for percent of basin cropped (assumes 100% of the crop treated).

IV. DEEM-FCID™ Program and Consumption Information

Acute and chronic dietary exposure assessments were conducted using DEEM-FCID™ (ver 2.03) which incorporates consumption data from USDA's CSFII (1994-1996 and 1998). The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or “matched” in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

V. Toxicological Information

The HED Hazard Identification Assessment Review Committee (HIARC) met on 14-September-1999 (HED Doc. No. 013765) and 13-May-2004 (TXR No. 0052657) to select endpoints for risk assessment and to evaluate the potential for increased susceptibility of infants and children from exposure to tetraconazole (evaluated according to the February 2002 OPP 10X guidance document). The HED Cancer Assessment Review Committee met on 10-November-1999 and classified tetraconazole as a likely human carcinogen (HED Doc. No. 013948). The HIARC, based on toxicological considerations, recommended for a 1x Food Quality Protection Act Safety Factor (FQPA SF). Based on toxicological considerations and the residue assumptions used in the dietary analyses, RABI concluded that the FQPA SF should be reduced to 1x when assessing dietary exposures. Table 6 summarizes the endpoints used for dietary exposure assessment.

Table 6: Summary of Toxicological Doses and Endpoints for Tetraconazole Dietary Exposure Assessment[1].

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Dose for Risk Assessment	Study and Toxicological Effects
Acute Dietary - general population (including infants and children)	NOAEL = 50 mg/kg/day UF = 100 **aRfD** = 0.50 mg/kg/day	FQPA SF = 1x **aPAD** = aRfD ÷ FQPA SF = 0.50 mg/kg	Acute neurotoxicity study - rat. LOAEL = 200 mg/kg/day due to decreased motor activity on day 0 in both sexes, and clinical signs in females including hunched posture, decreased defecation, and/or red or yellow material on various body surfaces.
Acute Dietary - Females 13-50 years of age	NOAEL = 22.5 mg/kg/day UF = 100 **aRfD** = 0.225 mg/kg/day	FQPA SF = 1x **aPAD** = aRfD ÷ FQPA SF = 0.225 mg/kg	Oral developmental toxicity study - rat. Developmental NOAEL = 22.5 mg/kg/day, based on increased incidence of small fetuses, and supernumerary ribs.
Chronic Dietary - all populations	NOAEL= 0.73 mg/kg/day UF =100 **cRfD** = 0.0073 mg/kg/day	FQPA SF = 1x **cPAD** = cRfD ÷ FQPA SF cPAD = 0.0073 mg/kg/day	Chronic oral toxicity - dog. Systemic Toxicity LOAEL = 2.95/3.33 (M/F) mg/kg/day, based on absolute and relative kidney weights and histopathological changes in the male kidney.
Cancer	Classification: “likely to be carcinogenic to humans” Q_1^*= 2.30×10^{-2}, based on male mouse liver benign and/or malignant combined tumor rates.		

1 NOAEL = no-observed-adverse-effect-level; LOAEL = lowest-observed-adverse-effect-level; UF = uncertainty factor; RfD = reference dose; PAD = population-adjusted dose = RfD ÷ FQPA SF.

VI. Results/Discussion

Acute: The unrefined acute analysis resulted in exposure estimates less than HED's level of concern (≤1.8% aPAD; children 1-2 years old were the most highly exposed population subgroup; see Table 7).

Chronic: The chronic analysis was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies, and projected percent crop treated estimates. The resulting exposure estimates are less than HED's level of concern (≤5% cPAD; all infants <1 year old were the most highly exposed population subgroup; see Table 7).

Cancer: The cancer analysis was refined through the incorporation of empirical processing factors, average field trial residues, average residues from the feeding studies, and projected percent crop treated estimates. The resulting exposures estimates yielded a cancer risk for the U.S. population of 3×10^{-6} (2.54×10^{-6} rounded to 3×10^{-6}; see Table 8).

Cancer risks presented in this assessment are expressed to one significant figure. However, it should be noted that, in general, the precision which can be assumed for cancer risk estimates is best described by rounding to the nearest integral order of magnitude on the log scale, e.g., 3.16×10^{-7} to 3.16×10^{-6}, expressed as 10^{-6}. Risks are generally reported to one significant figure in HED risk assessments to allow better characterization of *changes* in risk which might result from potential risk mitigation. This rounding procedure indicates that risks should generally not be assumed to exceed the benchmark level of concern of 10^{-6} until the calculated risks exceed approximately 3×10^{-6}. Discretion should be used in interpreting the significance of these calculated risks with consideration given to the precision in the risk estimates.

Table 7: Summary of the Acute and Chronic Dietary Exposure and Risk.

Population	aPAD (mg/kg/day)	Exposure (mg/kg/day)[1]	%aPAD	cPAD (mg/kg/day)	Exposure (mg/kg/day)	%cPAD
General U.S. Population	0.50	0.003570	<1	0.0073	0.000140	1.9
All Infants (< 1 year old)		0.006518	1.3		**0.000360**	**4.9**
Children 1-2 years old		**0.009120**	**1.8**		0.000274	3.8
Children 3-5 years old		0.006743	1.4		0.000247	3.4
Children 6-12 years old		0.004167	<1		0.000159	2.2
Youth 13-19 years old		0.002460	<1		0.000102	1.4
Adults 20-49 years old		0.002102	<1		0.000122	1.7
Adults 50+ years old		0.001807	<1		0.000129	1.8
Females 13-49 years old	0.225	0.002140	<1		0.000124	1.7

1 95th percentile (tier 1 analysis)

Table 8: Summary of the Cancer Dietary Exposure and Risk.

Population[1]	Exposure (mg/kg/day)	Q_1^*	Cancer risk
General U.S. population	0.000111	0.023	2.54×10^{-6}

1 exposure for the general U.S. population; HED performs cancer analyses for only the general U.S. population.

VII. Characterization of Inputs/Outputs

The acute analysis could be refined through the incorporation of anticipated residues, percent crop treated estimates, and/or monitoring data. The chronic/cancer analyses incorporated average field trial residues, average residues from the feeding studies, and/or projected percent crop treated and could be further refined through the incorporation of monitoring data. A critical commodity analysis for the cancer run (U.S. population) indicated that water (63% of total exposure), strawberry (11% of total exposure), dairy products (5% of total exposure), and soybean oil (4% of total exposure) were the major contributors to the cancer exposure.

VIII. Conclusions

The acute (≤1.8% of the aPAD), chronic (≤5% of the cPAD), and cancer (3×10^{-6}) exposure estimates are not of concern to HED.

Attachment 1: BEAD percent crop treated information (soybean (revised) and field corn)
Attachment 2: BEAD percent crop treated information (soybean, sugar beet, and peanut)
Attachment 3: DEEM-FCID™ acute exposure estimates
Attachment 4: DEEM-FCID™ acute residue file
Attachment 5: DEEM-FCID™ chronic exposure estimates
Attachment 6: DEEM-FCID™ chronic residue file
Attachment 7: DEEM-FCID™ cancer exposure estimates
Attachment 8: DEEM-FCID™ cancer residue file
Attachment 9: Critical Commodity Analysis for the Cancer Analysis

CC with attachments - Mary Waller/Lisa Jones (RM 21; 7505P) and Barbara Madden (RM 05; 7505P)
T. Bloem:S10945:PY:(703)605-0217:7509P

Attachment 1: BEAD percent crop treated information (soybean (revised) and field corn)

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III. PR

DMI and QoI fungicides would be relied on if soybean rust is predicted to be a problem, most likely tank-mixing active ingredients or using available pre-mixed DMI/QoI products to reduce the chance of resistance development by the pathogen (Tenuta et al., 2007). QoI fungicides are considered "high risk" for resistance by some pathogens, although resistance to the soybean rust pathogen has not been reported (FRAC, 2010).

Besides tetraconazole, other DMI fungicides registered for use against soybean rust include propiconazole, tebuconazole, cyproconazole, myclobutanil, and prothioconazole. All of these may not be registered for use in all states (Giesler and Gustafson, 2008). BEAD found no information that would suggest a preference of one DMI over another where a DMI fungicide was recommended for soybean rust management. QoI fungicides azoxystrobin, pyraclostrobin and trifloxystrobin are registered for soybean rust management. The chloronitrile fungicide, chlorothalonil may be used for rust suppression and for resistance management.

Fungicides are most effective when used as protectants against infection. The QoI fungicides are locally systemic and they prevent both spore germination and spore penetration into plant leaves. Prior to infection by the pathogen, chlorothalonil also exhibits protectant properties by inhibiting spore germination. Chlorothalonil is not systemic and is ineffective once fungal spores have germinated. Once infection has occurred, DMI fungicides may be applied due to their somewhat "curative" effect of inhibiting pathogen growth within the leaves. However, once disease develops to the point of cyclical production of spores, DMI fungicides will not be effective (Giesler and Gustafson, 2008).

Because early detection is the most effective means of managing rust, IPM strategies have been encouraged by extension specialists to determine the risk of rust and other soybean diseases developing (e.g., disease forecasting including proximity to diseased fields and weather conditions) before the expense and impacts of fungicide applications are undertaken. A fungicide application generally is considered between the start of flowering (R1) through the beginning of seed formation (R5) (Tenuta *et al.*, 2007). After R5, fungicides are not recommended.

For non-rust soybean foliar diseases fungicides are not used extensively (Tenuta *et al.*, 2007; Crop Profile for Soybeans in Mississippi, 2005; Giesler and Gustafson, 2008). For example, in Wisconsin the most prevalent diseases during trials in 2005 and 2006 were brown spot, downy mildew, powdery mildew, and frogeye leaf spot (UW Soybean Plant Health, 2007). It was not clear that fungicides were effective in controlling any of these diseases.

In the past two years, quinone inside inhibitor (QoI) fungicide products, such as azoxystrobin and pyraclostrobin have been marketed as "plant health promoters" for soybean and corn and have been said to increase yields under some conditions even in the absence of disease pressure. The use of fungicides where disease is not present or likely to occur has elicited debate in the extension and grower communities (e.g., Hershman and Vincelli, 2008; UW Soybean Plant Health, 2007; Corn and Soybean Digest, 2010). Any increased use of QoI fungicides for plant health improvement would not occur for tetraconazole, since DMI fungicides have not been associated with the potential yield and other physiological activities.

Attachment 2: BEAD percent crop treated information (soybean, sugar beet, and peanut)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

DEC 1 3 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Projected Percent Crop Treated for the Fungicide Tetraconazole (PC Code: 120603), (DP # 332043), on Three Crops: Peanuts, Soybeans, and Sugar Beets.

FROM: Jihad Alsadek, Economist Jihad A. Alsadek
Science Information & Analysis Branch
Biological and Economic Analysis Division (7503P)

Richard Michell, Plant Pathologist Richard Michell
Biological Analysis Branch
Biological and Economic Analysis Division (7503P)

TO: Mary Waller, Product Manager
Fungicide Branch
Registration Division (7505P)

PRP Review: November 29, 2006

I. SUMMARY

This memorandum provides projected percent crop treated (PPCT) values for tetraconazole on three crops (peanuts, soybeans, and sugar beets), as well as the corresponding Federal Register (FR) language. The methodology used to produce the estimates is outlined below, along with the analysis of additional biological information that could impact the assessments. The market leader approach is only used with peanuts; other approaches are used for soybeans and sugar beets. Input from the registrant Isa Gro and data from crop specialists are used for soybeans, and the sugar beet regional value is adjusted for a national one. We have examined all the relevant data and conclude that it is unlikely that the actual percent crop treated (PCT) values for tetraconazole on peanuts, soybeans and sugar beets in the next five years will exceed the PPCTs provided for tetraconazole on these three crops. Numbers to be used in risk analysis are shown in table 1.

Table 1. Values to be used in Risk Assessment

Crop	Chronic	Acute
Peanuts	77	88
Soybeans	27	38
Sugar Beets	70	70

II. FR LANGUAGE

EPA estimates projected percent crop treated (PPCT) for a new pesticide use by assuming that the percent crop treated (PCT) during the pesticide's initial five years of use on a specific use site will not exceed the average PCT of the market leader (i.e., the one with the greatest PCT) on that site.

Typically, EPA uses USDA/NASS as the primary source for PCT data. When a specific use site is not surveyed by USDA/NASS, EPA uses other sources including proprietary data and calculates the PCT. Comparisons are only made among pesticides of the same pesticide types (i.e., the leading fungicide on the use site is selected for comparison with the new fungicide). The PCTs included in the average may be for the same pesticide, or for different pesticides, since the same, or different pesticides, may dominate for each year selected. This PPCT, based on the average PCT of the market leader, is appropriate for use in chronic dietary risk assessment. The method of estimating a PPCT for a new use of a registered pesticide or a new pesticide produces a high-end estimate that is unlikely, in most cases, to be exceeded during the initial five years of actual use.

The predominant factors that bear on whether the estimated PPCT could be exceeded are whether new pesticide use or new pesticide is more efficacious or controls a broader spectrum of pests than the dominant pesticide; and/or whether there are concerns with pest pressures as indicated in emergency exemption requests or other readily available information; and/or other factor based on analysis of additional information, such as the total crop acreage and the geographical distribution of the crops and pests.

All information currently available for the predominant factors mentioned above or relevant to the case in question have been considered for this chemical, and it is the opinion of BEAD that it is unlikely that actual PCT for tetraconazole will exceed the PPCT during the next five years.

III. PROJECTIONS BASED ON MARKET LEADER APPROACH

The PPCTs for peanuts are calculated by averaging the PCTs of the leading fungicide(s) for the three most recent available years. The PPCT for sugar beets showed a 55 percent use of tetraconazole as the market leader for the year 2000, but 2000 USDA/NASS data for the market leader tetraconazole is registered on sugar beets in seven states (Colorado, Michigan, Minnesota, Montana, Nebraska, North Dakota, and Wyoming). NASS data are adjusted to get the acres treated in each of the seven states, summing them up, then dividing by the sum of the planted acres in these same states, and multiplying by 100 to get, on average, market leader for sugar beets to be used in chronic dietary risk assessment and acute risk too.

The PPCTs for soybeans were based on a modified approach which is described in the following subsection (Modified PPCT Approach for Soybeans).

Table 2. Projected Tetraconazole PCT Values for Dietary Risk Assessments

Crop	Market Leaders[a]	Average[b] Market Leader	Maximum[c] Market Leader	Years
Peanuts	Chlorothalonil	77	88	1991, 1999, 2004
Soybeans	Unknown, but projected to be a triazole and/or strobilurin fungicide	27	38	Future projection for next 5 years
Sugar Beets	Tetraconazole	70	70	Adjusted for year 2000

Sources: Based on 1991 to 2004 NASS usage data for peanuts and sugar beets. Crop Specialists' usage projections were used for soybeans.
[a] Market leaders could be the same chemical for all three years or could be different for each year.
[b] Averaging the available years.
[c] The highest observed percent crop treated of the available survey years.

IV. Modified PPCT Approach for Soybeans

Due to the recent discovery of a new and important disease on soybeans, Asian soybean rust, historical information was not considered useful for estimating a useful PCT for a fungicide market leader on soybeans. Another approach was utilized which involved obtaining PCT estimates for future market leaders from soybean crop specialists. The estimates were obtained via a phone call and four list server responses enlisted by USDA. The five crop specialists' PCT estimates for a market leader ranged from 10 to 38 percent. For a conservative estimate we utilized only the maximum projected values provided by each respondent, which ranged from 15 to 38 percent. These values translated into average and maximum PPCT values of 27 and 38 percent, respectively.

The most common factors used by the crop specialists to project the market leader PCT were: weather patterns; prevailing winds; length of time crop is in a growth stage that will lead to yield losses, if infection occurs during this period; cost-effectiveness of treatments; and market supply/availability limitations. Some of the specific examples provided to support their estimates were:

a) About 21% of the total soybean acreage is in areas where the prevailing winds and temperature and humidity are generally unfavorable for soybean rust infection (e.g., KS, ND, NE, SD).

b) About 16% of the total soybean acreage doesn't have the yield potential to justify the cost of a soybean rust fungicide treatment.

c) In most years 40% of the soybean acreage is considered to possess a high risk for soybean rust infection (e.g., IL, IN, OH, AR, eastern MO).

d) Pesticide distributors are more likely to carry stock of those soybean rust fungicides that have other labeled uses relevant to area growers (e.g., wheat and corn uses in Midwestern states). Note: The only alternate crop uses for tetraconazole are sugar beets and peanuts, which are not prevalent crops in most soybean production areas.

V. ADDITIONAL FACTORS

Table 3. Biological Analysis of BEAD's Projected Percent Crop Treated (PPCT) for Tetraconazole on Three New Crops

NEW USES [AVG. /MAX. PPCT]	**RECENT MARKET LEADER(S) [SAMPLE YEARS]**	**JUSTIFICATION/COMMENTS**	**WILL TETRACONAZOLE EXCEED THE PCT LEVELS OF MARKET LEADER(S)?**
Sugar Beets – cercospora leaf spot, powdery mildew [70/70]	tetraconazole [2000]	Tetraconazole is the current market leader (55%), and was previously only registered for use in 7 sugar beet producing states (CO, MI, MN, MT, NE, ND, WY); based on the 2006 acreage planted, the addition of 4 states (CA, ID, OR, WA) increases the potential acreage to be treated by about 18 percent; if all the planted acreage in these 4 additional states are treated it could bring the PPCT up to about 77%; based upon the pest information provided in the USDA Crop Profiles it is not likely that more than 70% of the planted acreage will be treated in any of the 4 additional states, because the reported <u>total fungicide</u> usage for these target pests is less than	No

NEW USES [AVG. /MAX. PPCT]	RECENT MARKET LEADER(S) [SAMPLE YEARS]	JUSTIFICATION/COMMENTS	WILL TETRACONAZOLE EXCEED THE PCT LEVELS OF MARKET LEADER(S)?
		70%	
Soybeans – Asian soybean rust, cercospora, frog eye, white mold, powdery mildew, septoria, anthracnose [27/38]	Not applicable	These values seem to be reasonable estimates for the future market leader(s) when the following factors are considered: 1] at least 11 active ingredients are currently available and competing for the Asian soybean rust control market on the approximately 75 million acres grown; 2] treatments are only warranted when weather conditions conducive to disease development occur during the soybean bloom and/or pod fill stages; 3] in any given year the probability of a national epidemic which results in the need for most of the US acreage grown in the 31 soybean producing states being treated is low, because it would be dependent upon the widespread occurrence of unusual weather patterns during the critical crop growth stages; 4] The proposed labeling allows for up to two applications per year, which if it occurs will reduce stocks and therefore reduce the total acreage capable of being treated; Some of the crop specialists projected that up to 30 - 40% of the acreage in their state may be treated twice. 5] the registrant stated that only one tetraconazole product will be marketed for the soybean use because the chemical is still under patent, which would appear to limit the amount likely to be available throughout the US due to supply limitations and surplus stock concerns if	No, plus the likelihood of an epidemic although uncertain is thought to be low

NEW USES [AVG. /MAX. PPCT]	RECENT MARKET LEADER(S) [SAMPLE YEARS]	JUSTIFICATION/COMMENTS	WILL TETRACONAZOLE EXCEED THE PCT LEVELS OF MARKET LEADER(S)?
		an epidemic does not occur; 6] The registrant (Isa Gro), per a personal phone call on November 16, 2006, stated that although they projected they might be able to treat as much as 5.38% of the crop if an epidemic occurred; they felt it would be impossible to supply enough tetraconazole to treat 10% of the crop anytime within the next 5 years. 7] Since the disease organism is not considered cold-hardy, each growing season the disease must start its northward movement from Mexico and/or extreme southern United States locations. Accordingly, the northward disease spread each year and the specific states impacted is dependent upon wind speed and direction during humid and moderate temperature weather. 8] EPA has approved a wide range of active ingredients and products that can be available to growers. This effort was initiated because of national concern that the supply of fungicides would not be adequate in the case of a soybean rust epidemic. This involved granting numerous states permission to use seven active ingredients via Section 18 quarantine emergency exemptions, in addition to the four active ingredients already available via Section 3 registrations. 9] Based on yields obtained in recent soybean rust efficacy studies conducted in the US and other countries the triazole and	

NEW USES [AVG. /MAX. PPCT]	**RECENT MARKET LEADER(S) [SAMPLE YEARS]**	**JUSTIFICATION/COMMENTS**	**WILL TETRACONAZOLE EXCEED THE PCT LEVELS OF MARKET LEADER(S)?**
		strobilurin fungicide classes generally seem to be the most efficacious groups of fungicides to use (Fungicide & Nematicide Tests – Special Section on Asian Soybean Rust Reports; http://www.apsnet.org/online/FNtests/). Most crop specialists predict combinations of these two types of fungicides will be used by many growers. 10] Since the competing fungicide tebuconazole is reportedly among the least expensive fungicides, as well as one of the most effective triazole fungicides, it is generally considered by crop specialists to be the triazole fungicide of choice. Since there are multiple products (alone and in combinations with other fungicides) being sold by different companies reasonable stocks are expected to be available in most soybean production areas. 11] Crop specialists projected that the maximum US soybean acreage to be treated with a fungicide, if an epidemic occurred, would range from 35-65 percent (average = 54%). Therefore if one of the eleven active ingredients available were able to attain a 50% market share this would only result in a maximum of 32.5% of the crop being treated with any one fungicide. BEAD contends that this level of market share is rarely achieved when a number of competitive active ingredients are available.	
Peanuts – early leaf spot, late leaf spot,	chlorothalonil [1991, 1999, 2004]	The market leader chlorothalonil is typically inexpensive and is used mainly for control of the same pests that are claimed on the proposed tetraconazole	No

7

NEW USES [AVG. /MAX. PPCT]	RECENT MARKET LEADER(S) [SAMPLE YEARS]	JUSTIFICATION/COMMENTS	WILL TETRACONAZOLE EXCEED THE PCT LEVELS OF MARKET LEADER(S)?
web blotch, rust [77/88]		label plus the common and important disease white mold (southern stem rot); chlorothalonil is alternated with various systemic fungicides to delay the development of resistant pest strains; the introduction of the systemic fungicide tetraconazole will not likely affect chlorothalonil's current usage, but it is expected to share the existing systemic fungicide market	

VI. CONCLUSIONS/RECOMMENDATIONS

BEAD recommends that the given average PPCTs be used in the chronic dietary risk assessment for tetraconazole, and the maximum PPCTs for acute risk assessment. BEAD has considered all relevant information and believes it is unlikely that the above PPCTs will be exceeded during the next five years for peanuts, soybeans, and sugar beets.

VII. References:

Typically, EPA uses USDA/NASS as the source for raw PCT data because it is publicly available and does not have to be calculated from available data sources. When a specific use site is not surveyed by USDA/NASS, EPA uses proprietary data and calculates the estimated PCT.

Agricultural Chemical Usage, 1990 Field Crops Summary, May 1991

Agricultural Chemical Usage, 1998 Field Crops Summary, May 1999

Agricultural Chemical Usage, 1999 Field Crops Summary, May 2000

Agricultural Chemical Usage, 2004 Field Crops Summary, May 2005

USDA, 1999, Crop Profile for Sugar Beet in California.
http://www.ipmcenters.org/cropprofiles/docs/casugarbeets.html

USDA, 2000. Crop Profile for Sugar Beet in Idaho.
http://www.ipmcenters.org/cropprofiles/docs/IDsugarbeets.html

USDA, 1999, Crop Profile for Sugar Beet in Oregon.
http://www.ipmcenters.org/cropprofiles/docs/orsugarbeets.html

USDA, 2001, Crop Profile for Sugar Beet in Washington.
http://www.ipmcenters.org/cropprofiles/docs/WAsugarbeets.html

cc: Lisa Jones
Thomas Bloem
Dana Spatz

9

Attachment 3: DEEM-FCID™ acute exposure estimates

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U.S. Environmental Protection Agency                                Ver. 2.02
DEEM-FCID ACUTE Analysis for TETRACONAZOLE                     (1994-98 data)
Residue file: 120603a.R98                         Adjustment factor #2 NOT used.
Analysis Date: 04-13-2011/14:21:50    Residue file dated: 04-13-2011/14:05:00/8
Daily totals for food and foodform consumption used.
Run Comment: "acute for females 13-50 only = 0.225 mg/kg/day; acute for remain
ing populations = 0.50 mg/kg/day"
===============================================================================
```

Summary calculations (per capita):

	95th Percentile		99th Percentile		99.9th Percentile	
	Exposure	% aRfD	Exposure	% aRfD	Exposure	% aRfD
U.S. Population:	0.003570	0.71	0.006349	1.27	0.011921	2.38
U.S. Population (spring season):	0.003679	0.74	0.006256	1.25	0.010983	2.20
U.S. Population (summer season):	0.003693	0.74	0.006437	1.29	0.011909	2.38
U.S. Population (autumn season):	0.003463	0.69	0.006339	1.27	0.012775	2.55
U.S. Population (winter season):	0.003457	0.69	0.006285	1.26	0.011662	2.33
Northeast region:	0.003661	0.73	0.006439	1.29	0.011755	2.35
Midwest region:	0.003666	0.73	0.006512	1.30	0.012266	2.45
Southern region:	0.003379	0.68	0.006255	1.25	0.011801	2.36
Western region:	0.003684	0.74	0.006191	1.24	0.010944	2.19
Hispanics:	0.004066	0.81	0.006975	1.40	0.011622	2.32
Non-hispanic whites:	0.003434	0.69	0.006112	1.22	0.011778	2.36
Non-hispanic blacks:	0.003724	0.74	0.006761	1.35	0.013687	2.74
Non-hisp/non-white/non-black:	0.003708	0.74	0.006455	1.29	0.010834	2.17
All infants:	0.006518	1.30	0.010646	2.13	0.017666	3.53
Nursing infants (<1 yr old):	0.003413	0.68	0.007047	1.41	0.011544	2.31
Non-nursing infants (<1 yr old):	0.007054	1.41	0.011482	2.30	0.018051	3.61
Children 1-6 yrs:	0.007570	1.51	0.011743	2.35	0.019681	3.94
Children 7-12 yrs:	0.003873	0.77	0.005563	1.11	0.009534	1.91
Males 13-19 yrs:	0.002596	0.52	0.003955	0.79	0.008244	1.65
Males 20+ yrs:	0.002014	0.40	0.003009	0.60	0.004610	0.92
Seniors 55+:	0.001833	0.37	0.002884	0.58	0.004612	0.92
Children 1-2 yrs:	0.009120	1.82	0.014111	2.82	0.032922	6.58
Children 3-5 yrs:	0.006743	1.35	0.010236	2.05	0.017345	3.47
Children 6-12 yrs:	0.004167	0.83	0.006023	1.20	0.010267	2.05
Youth 13-19 yrs:	0.002460	0.49	0.003603	0.72	0.005666	1.13
Adults 20-49 yrs:	0.002102	0.42	0.003145	0.63	0.004923	0.98
Adults 50+ yrs:	0.001807	0.36	0.002872	0.57	0.004601	0.92

```
U.S. Environmental Protection Agency                                 Ver. 2.02
DEEM-FCID ACUTE Analysis for TETRACONAZOLE                       (1994-98 data)
Residue file: 120603a.R98                         Adjustment factor #2 NOT used.
Analysis Date: 04-13-2011/14:23:23    Residue file dated: 04-13-2011/14:05:00/8
Daily totals for food and foodform consumption used.
Run Comment: "acute for females 13-50 only = 0.225 mg/kg/day; acute for remain
ing populations = 0.50 mg/kg/day"
===============================================================================
Summary calculations (per capita):
                    95th Percentile      99th Percentile      99.9th Percentile
                   Exposure   % aRfD    Exposure   % aRfD    Exposure   % aRfD
                  ---------- --------  ---------- --------  ---------- --------
Females 13+ (preg/not nursing):
                    0.002685     1.19    0.002927     1.30    0.003475     1.54
Females 13+ (nursing):
                    0.002520     1.12    0.003000     1.33    0.003124     1.39
Females 13-19 (not preg or nursing):
                    0.002148     0.95    0.003211     1.43    0.005435     2.42
Females 20+ (not preg or nursing):
                    0.001958     0.87    0.003074     1.37    0.004921     2.19
Females 13-50 yrs:
                    0.002127     0.95    0.003122     1.39    0.004988     2.22
Females 13-49 yrs:
                    0.002140     0.95    0.003129     1.39    0.005001     2.22
```

Attachment 4: DEEM-FCID™ acute residue file

```
Filename: C:\Documents and Settings\tbloem\tetraconazole\corn and small fruit vine and
climbing subgroup except fuzzy kiwifruit\120603a.R98
Chemical: tetraconazole
RfD(Chronic): .0073 mg/kg bw/day  NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .5 mg/kg bw/day  NOEL(Acute):  0 mg/kg bw/day Q*= .023
Date created/last modified: 04-13-2011/14:05:00/8          Program ver. 2.03
Comment: acute for females 13-50 only = 0.225 mg/kg/day; acute for remaining populations
= 0.50 mg/kg/day
```

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
01010520	1A	Beet, sugar	0.150000	1.000	1.000	
01010521	1A	Beet, sugar-babyfood	0.150000	1.000	1.000	
01010530	1A	Beet, sugar, molasses	0.315000	1.000	1.000	
01010531	1A	Beet, sugar, molasses-babyfood	0.315000	1.000	1.000	
06003470	6	Soybean, seed	0.150000	1.000	1.000	
06003480	6	Soybean, flour	0.150000	1.000	1.000	
06003481	6	Soybean, flour-babyfood	0.150000	1.000	1.000	
06003490	6	Soybean, soy milk	0.150000	1.000	1.000	
06003491	6	Soybean, soy milk-babyfood or in	0.150000	1.000	1.000	
06003500	6	Soybean, oil	0.800000	1.000	1.000	
06003501	6	Soybean, oil-babyfood	0.800000	1.000	1.000	
13020570	13B	Blueberry	0.332000	1.000	1.000	
13020571	13B	Blueberry-babyfood	0.332000	1.000	1.000	
13021740	13B	Gooseberry	0.266000	1.000	1.000	
14002690	14	Pecan	0.050000	1.000	1.000	
15001200	15	Corn, field, flour	0.010000	1.000	1.000	
15001201	15	Corn, field, flour-babyfood	0.010000	1.000	1.000	
15001210	15	Corn, field, meal	0.010000	1.000	1.000	
15001211	15	Corn, field, meal-babyfood	0.010000	1.000	1.000	
15001220	15	Corn, field, bran	0.010000	1.000	1.000	
15001230	15	Corn, field, starch	0.010000	1.000	1.000	
15001231	15	Corn, field, starch-babyfood	0.010000	1.000	1.000	
15001240	15	Corn, field, syrup	0.010000	1.500	1.000	
15001241	15	Corn, field, syrup-babyfood	0.010000	1.500	1.000	
15001250	15	Corn, field, oil	0.010000	1.000	1.000	
15001251	15	Corn, field, oil-babyfood	0.010000	1.000	1.000	
15001260	15	Corn, pop	0.010000	1.000	1.000	
21000440	M	Beef, meat	0.010000	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.010000	1.000	1.000	
21000450	M	Beef, meat, dried	0.010000	1.920	1.000	
21000460	M	Beef, meat byproducts	0.150000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.150000	1.000	1.000	
21000470	M	Beef, fat	0.150000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.150000	1.000	1.000	
21000480	M	Beef, kidney	0.150000	1.000	1.000	
21000490	M	Beef, liver	1.500000	1.000	1.000	
21000491	M	Beef, liver-babyfood	1.500000	1.000	1.000	
23001690	M	Goat, meat	0.010000	1.000	1.000	
23001700	M	Goat, meat byproducts	0.150000	1.000	1.000	
23001710	M	Goat, fat	0.150000	1.000	1.000	
23001720	M	Goat, kidney	0.150000	1.000	1.000	
23001730	M	Goat, liver	1.500000	1.000	1.000	
24001890	M	Horse, meat	0.010000	1.000	1.000	
25002900	M	Pork, meat	0.010000	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.010000	1.000	1.000	
25002910	M	Pork, skin	0.010000	1.000	1.000	
25002920	M	Pork, meat byproducts	0.010000	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.010000	1.000	1.000	
25002930	M	Pork, fat	0.010000	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.010000	1.000	1.000	
25002940	M	Pork, kidney	0.010000	1.000	1.000	
25002950	M	Pork, liver	0.050000	1.000	1.000	
26003390	M	Sheep, meat	0.010000	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.010000	1.000	1.000	

26003400	M	Sheep, meat byproducts	0.150000	1.000	1.000
26003410	M	Sheep, fat	0.150000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.150000	1.000	1.000
26003420	M	Sheep, kidney	0.150000	1.000	1.000
26003430	M	Sheep, liver	1.500000	1.000	1.000
27002220	D	Milk, fat	0.750000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.750000	1.000	1.000
27012230	D	Milk, nonfat solids	0.030000	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.030000	1.000	1.000
27022240	D	Milk, water	0.030000	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.030000	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.030000	1.000	1.000
28002210	M	Meat, game	0.010000	1.000	1.000
29003120	M	Rabbit, meat	0.010000	1.000	1.000
40000930	P	Chicken, meat	0.010000	1.000	1.000
40000931	P	Chicken, meat-babyfood	0.010000	1.000	1.000
40000940	P	Chicken, liver	0.050000	1.000	1.000
40000950	P	Chicken, meat byproducts	0.050000	1.000	1.000
40000951	P	Chicken, meat byproducts-babyfoo	0.050000	1.000	1.000
40000960	P	Chicken, fat	0.050000	1.000	1.000
40000961	P	Chicken, fat-babyfood	0.050000	1.000	1.000
40000970	P	Chicken, skin	0.050000	1.000	1.000
40000971	P	Chicken, skin-babyfood	0.050000	1.000	1.000
50003820	P	Turkey, meat	0.010000	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.010000	1.000	1.000
50003830	P	Turkey, liver	0.050000	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.050000	1.000	1.000
50003840	P	Turkey, meat byproducts	0.050000	1.000	1.000
50003841	P	Turkey, meat byproducts-babyfood	0.050000	1.000	1.000
50003850	P	Turkey, fat	0.050000	1.000	1.000
50003851	P	Turkey, fat-babyfood	0.050000	1.000	1.000
50003860	P	Turkey, skin	0.050000	1.000	1.000
50003861	P	Turkey, skin-babyfood	0.050000	1.000	1.000
60003010	P	Poultry, other, meat	0.010000	1.000	1.000
60003020	P	Poultry, other, liver	0.050000	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.050000	1.000	1.000
60003040	P	Poultry, other, fat	0.050000	1.000	1.000
60003050	P	Poultry, other, skin	0.050000	1.000	1.000
70001450	P	Egg, whole	0.020000	1.000	1.000
70001451	P	Egg, whole-babyfood	0.020000	1.000	1.000
70001460	P	Egg, white	0.020000	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.020000	1.000	1.000
70001470	P	Egg, yolk	0.020000	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.020000	1.000	1.000
86010000	O	Water, direct, all sources	0.010450	1.000	1.000
86020000	O	Water, indirect, all sources	0.010450	1.000	1.000
95001750	O	Grape	0.266000	1.000	1.000
95001760	O	Grape, juice	0.266000	1.000	1.000
95001761	O	Grape, juice-babyfood	0.266000	1.000	1.000
95001770	O	Grape, leaves	0.266000	1.000	1.000
95001780	O	Grape, raisin	0.266000	1.000	1.000
95001790	O	Grape, wine and sherry	0.266000	1.000	1.000
95001950	O	Kiwifruit	0.266000	1.000	1.000
95002630	O	Peanut	0.038000	1.000	1.000
95002640	O	Peanut, butter	0.038000	1.890	1.000
95002650	O	Peanut, oil	0.126000	1.000	1.000
95003590	O	Strawberry	0.332000	1.000	1.000
95003591	O	Strawberry-babyfood	0.332000	1.000	1.000
95003600	O	Strawberry, juice	0.332000	1.000	1.000
95003601	O	Strawberry, juice-babyfood	0.332000	1.000	1.000

Attachment 5: DEEM-FCID™ chronic exposure estimates

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U.S. Environmental Protection Agency                              Ver. 2.00
DEEM-FCID Chronic analysis for TETRACONAZOLE                   (1994-98 data)
Residue file name: C:\Documents and Settings\tbloem\tetraconazole\corn and small fruit
vine and climbing subgroup except fuzzy kiwifruit\120603c.R98
                                                     Adjustment factor #2 used.
Analysis Date 04-13-2011/14:10:08     Residue file dated: 04-13-2011/14:05:25/8
Reference dose (RfD, Chronic) = .0073 mg/kg bw/day
COMMENT 1: acute for females 13-50 only = 0.225 mg/kg/day; acute for remaining
populations = 0.50 mg/kg/day
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
```

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.000140	1.9%
U.S. Population (spring season)	0.000144	2.0%
U.S. Population (summer season)	0.000151	2.1%
U.S. Population (autumn season)	0.000132	1.8%
U.S. Population (winter season)	0.000133	1.8%
Northeast region	0.000133	1.8%
Midwest region	0.000142	2.0%
Southern region	0.000129	1.8%
Western region	0.000160	2.2%
Hispanics	0.000147	2.0%
Non-hispanic whites	0.000140	1.9%
Non-hispanic blacks	0.000125	1.7%
Non-hisp/non-white/non-black	0.000158	2.2%
All infants (< 1 year)	0.000360	4.9%
Nursing infants	0.000137	1.9%
Non-nursing infants	0.000445	6.1%
Children 1-6 yrs	0.000249	3.4%
Children 7-12 yrs	0.000151	2.1%
Females 13-19 (not preg or nursing)	0.000098	1.3%
Females 20+ (not preg or nursing)	0.000131	1.8%
Females 13-50 yrs	0.000129	1.8%
Females 13+ (preg/not nursing)	0.000133	1.8%
Females 13+ (nursing)	0.000188	2.6%
Males 13-19 yrs	0.000104	1.4%
Males 20+ yrs	0.000117	1.6%
Seniors 55+	0.000130	1.8%
Children 1-2 yrs	0.000274	3.8%
Children 3-5 yrs	0.000247	3.4%
Children 6-12 yrs	0.000159	2.2%
Youth 13-19 yrs	0.000102	1.4%
Adults 20-49 yrs	0.000122	1.7%
Adults 50+ yrs	0.000129	1.8%
Females 13-49 yrs	0.000124	1.7%

Attachment 6: DEEM-FCID™ chronic residue file

Filename: C:\Documents and Settings\tbloem\tetraconazole\corn and small fruit vine and climbing subgroup except fuzzy kiwifruit\120603c.R98
Chemical: tetraconazole
RfD(Chronic): .0073 mg/kg bw/day NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .225 mg/kg bw/day NOEL(Acute): 0 mg/kg bw/day Q*= .023
Date created/last modified: 04-13-2011/14:05:25/8 Program ver. 2.03
Comment: acute for females 13-50 only = 0.225 mg/kg/day; acute for remaining populations = 0.50 mg/kg/day

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	Adj.Factors #2	Comment
01010520	1A	Beet, sugar	0.005000	1.000	0.700	
01010521	1A	Beet, sugar-babyfood	0.005000	1.000	0.700	
01010530	1A	Beet, sugar, molasses	0.141000	1.000	0.700	
01010531	1A	Beet, sugar, molasses-babyfood	0.141000	1.000	0.700	
06003470	6	Soybean, seed	0.046000	1.000	0.050	
06003480	6	Soybean, flour	0.046000	1.000	0.050	
06003481	6	Soybean, flour-babyfood	0.046000	1.000	0.050	
06003490	6	Soybean, soy milk	0.046000	1.000	0.050	
06003491	6	Soybean, soy milk-babyfood or in	0.046000	1.000	0.050	
06003500	6	Soybean, oil	0.212000	1.000	0.050	
06003501	6	Soybean, oil-babyfood	0.212000	1.000	0.050	
13020570	13B	Blueberry	0.121000	1.000	1.000	
13020571	13B	Blueberry-babyfood	0.121000	1.000	1.000	
13021740	13B	Gooseberry	0.041000	1.000	1.000	
14002690	14	Pecan	0.009000	1.000	1.000	
15001200	15	Corn, field, flour	0.005000	1.000	0.090	
15001201	15	Corn, field, flour-babyfood	0.005000	1.000	0.090	
15001210	15	Corn, field, meal	0.005000	1.000	0.090	
15001211	15	Corn, field, meal-babyfood	0.005000	1.000	0.090	
15001220	15	Corn, field, bran	0.005000	1.000	0.090	
15001230	15	Corn, field, starch	0.005000	1.000	0.090	
15001231	15	Corn, field, starch-babyfood	0.005000	1.000	0.090	
15001240	15	Corn, field, syrup	0.005000	1.500	0.090	
15001241	15	Corn, field, syrup-babyfood	0.005000	1.500	0.090	
15001250	15	Corn, field, oil	0.005000	1.000	0.090	
15001251	15	Corn, field, oil-babyfood	0.005000	1.000	0.090	
15001260	15	Corn, pop	0.005000	1.000	1.000	
21000440	M	Beef, meat	0.000300	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.000300	1.000	1.000	
21000450	M	Beef, meat, dried	0.000300	1.920	1.000	
21000460	M	Beef, meat byproducts	0.003000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.003000	1.000	1.000	
21000470	M	Beef, fat	0.003000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.003000	1.000	1.000	
21000480	M	Beef, kidney	0.001000	1.000	1.000	
21000490	M	Beef, liver	0.044000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.044000	1.000	1.000	
23001690	M	Goat, meat	0.000300	1.000	1.000	
23001700	M	Goat, meat byproducts	0.003000	1.000	1.000	
23001710	M	Goat, fat	0.003000	1.000	1.000	
23001720	M	Goat, kidney	0.001000	1.000	1.000	
23001730	M	Goat, liver	0.044000	1.000	1.000	
24001890	M	Horse, meat	0.000300	1.000	1.000	
25002900	M	Pork, meat	0.000010	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.000010	1.000	1.000	
25002910	M	Pork, skin	0.000100	1.000	1.000	
25002920	M	Pork, meat byproducts	0.000100	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.000100	1.000	1.000	
25002930	M	Pork, fat	0.000100	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.000100	1.000	1.000	
25002940	M	Pork, kidney	0.000050	1.000	1.000	
25002950	M	Pork, liver	0.002000	1.000	1.000	
26003390	M	Sheep, meat	0.000300	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.000300	1.000	1.000	

26003400	M	Sheep, meat byproducts	0.003000	1.000	1.000
26003410	M	Sheep, fat	0.003000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.003000	1.000	1.000
26003420	M	Sheep, kidney	0.001000	1.000	1.000
26003430	M	Sheep, liver	0.044000	1.000	1.000
27002220	D	Milk, fat	0.010000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.010000	1.000	1.000
27012230	D	Milk, nonfat solids	0.000400	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.000400	1.000	1.000
27022240	D	Milk, water	0.000400	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.000400	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.000400	1.000	1.000
28002210	M	Meat, game	0.000300	1.000	1.000
29003120	M	Rabbit, meat	0.000300	1.000	1.000
40000930	P	Chicken, meat	0.000100	1.000	1.000
40000931	P	Chicken, meat-babyfood	0.000100	1.000	1.000
40000940	P	Chicken, liver	0.000600	1.000	1.000
40000950	P	Chicken, meat byproducts	0.002000	1.000	1.000
40000951	P	Chicken, meat byproducts-babyfoo	0.002000	1.000	1.000
40000960	P	Chicken, fat	0.002000	1.000	1.000
40000961	P	Chicken, fat-babyfood	0.002000	1.000	1.000
40000970	P	Chicken, skin	0.002000	1.000	1.000
40000971	P	Chicken, skin-babyfood	0.002000	1.000	1.000
50003820	P	Turkey, meat	0.000100	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.000100	1.000	1.000
50003830	P	Turkey, liver	0.000600	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.000600	1.000	1.000
50003840	P	Turkey, meat byproducts	0.002000	1.000	1.000
50003841	P	Turkey, meat byproducts-babyfood	0.002000	1.000	1.000
50003850	P	Turkey, fat	0.002000	1.000	1.000
50003851	P	Turkey, fat-babyfood	0.002000	1.000	1.000
50003860	P	Turkey, skin	0.002000	1.000	1.000
50003861	P	Turkey, skin-babyfood	0.002000	1.000	1.000
60003010	P	Poultry, other, meat	0.000100	1.000	1.000
60003020	P	Poultry, other, liver	0.000600	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.002000	1.000	1.000
60003040	P	Poultry, other, fat	0.002000	1.000	1.000
60003050	P	Poultry, other, skin	0.002000	1.000	1.000
70001450	P	Egg, whole	0.000500	1.000	1.000
70001451	P	Egg, whole-babyfood	0.000500	1.000	1.000
70001460	P	Egg, white	0.000500	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.000500	1.000	1.000
70001470	P	Egg, yolk	0.000500	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.000500	1.000	1.000
86010000	O	Water, direct, all sources	0.004680	1.000	1.000
86020000	O	Water, indirect, all sources	0.004680	1.000	1.000
95001750	O	Grape	0.041000	1.000	1.000
95001760	O	Grape, juice	0.002000	1.000	1.000
95001761	O	Grape, juice-babyfood	0.002000	1.000	1.000
95001770	O	Grape, leaves	0.041000	1.000	1.000
95001780	O	Grape, raisin	0.038000	1.000	1.000
95001790	O	Grape, wine and sherry	0.041000	1.000	1.000
95001950	O	Kiwifruit	0.041000	1.000	1.000
95002630	O	Peanut	0.016000	1.000	0.770
95002640	O	Peanut, butter	0.016000	1.890	0.770
95002650	O	Peanut, oil	0.054000	1.000	0.770
95003590	O	Strawberry	0.121000	1.000	1.000
95003591	O	Strawberry-babyfood	0.121000	1.000	1.000
95003600	O	Strawberry, juice	0.121000	1.000	1.000
95003601	O	Strawberry, juice-babyfood	0.121000	1.000	1.000

Attachment 7: DEEM-FCID™ cancer exposure estimates

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U.S. Environmental Protection Agency                                 Ver. 2.00
DEEM-FCID Chronic analysis for TETRACONAZOLE                     (1994-98 data)
Residue file name: C:\Documents and Settings\tbloem\tetraconazole\corn and small fruit
vine and climbing subgroup except fuzzy kiwifruit\120603cancer.R98
                                                     Adjustment factor #2 used.
Analysis Date 04-13-2011/14:10:31     Residue file dated: 04-13-2011/14:06:02/8
Q* = 0.023
COMMENT 1: acute for females 13-50 only = 0.225 mg/kg/day; acute for remaining
populations = 0.50 mg/kg/day
===============================================================================
                    Total exposure by population subgroup
-------------------------------------------------------------------------------
                                                    Total Exposure
                                            -----------------------------------
          Population                          mg/kg         Lifetime risk
           Subgroup                         body wt/day      (Q*= .023)
--------------------------------------    -------------    -------------
U.S. Population (total)                      0.000111        2.54E-06

-------------------------------------------------------------------------------
```

Attachment 8: DEEM-FCID™ cancer residue file

```
Filename: C:\Documents and Settings\tbloem\tetraconazole\corn and small fruit vine and
climbing subgroup except fuzzy kiwifruit\120603cancer.R98
Chemical: tetraconazole
RfD(Chronic): .0073 mg/kg bw/day  NOEL(Chronic): 0 mg/kg bw/day
RfD(Acute): .225 mg/kg bw/day  NOEL(Acute):  0 mg/kg bw/day Q*= .023
Date created/last modified: 04-13-2011/14:06:02/8          Program ver. 2.03
Comment: acute for females 13-50 only = 0.225 mg/kg/day; acute for remaining populations
= 0.50 mg/kg/day
```

EPA Code	Crop Grp	Commodity Name	Def Res (ppm)	Adj.Factors #1	#2	Comment
01010520	1A	Beet, sugar	0.005000	1.000	0.700	
01010521	1A	Beet, sugar-babyfood	0.005000	1.000	0.700	
01010530	1A	Beet, sugar, molasses	0.141000	1.000	0.700	
01010531	1A	Beet, sugar, molasses-babyfood	0.141000	1.000	0.700	
06003470	6	Soybean, seed	0.046000	1.000	0.050	
06003480	6	Soybean, flour	0.046000	1.000	0.050	
06003481	6	Soybean, flour-babyfood	0.046000	1.000	0.050	
06003490	6	Soybean, soy milk	0.046000	1.000	0.050	
06003491	6	Soybean, soy milk-babyfood or in	0.046000	1.000	0.050	
06003500	6	Soybean, oil	0.212000	1.000	0.050	
06003501	6	Soybean, oil-babyfood	0.212000	1.000	0.050	
13020570	13B	Blueberry	0.121000	1.000	1.000	
13020571	13B	Blueberry-babyfood	0.121000	1.000	1.000	
13021740	13B	Gooseberry	0.041000	1.000	1.000	
14002690	14	Pecan	0.009000	1.000	1.000	
15001200	15	Corn, field, flour	0.005000	1.000	0.090	
15001201	15	Corn, field, flour-babyfood	0.005000	1.000	0.090	
15001210	15	Corn, field, meal	0.005000	1.000	0.090	
15001211	15	Corn, field, meal-babyfood	0.005000	1.000	0.090	
15001220	15	Corn, field, bran	0.005000	1.000	0.090	
15001230	15	Corn, field, starch	0.005000	1.000	0.090	
15001231	15	Corn, field, starch-babyfood	0.005000	1.000	0.090	
15001240	15	Corn, field, syrup	0.005000	1.500	0.090	
15001241	15	Corn, field, syrup-babyfood	0.005000	1.500	0.090	
15001250	15	Corn, field, oil	0.005000	1.000	0.090	
15001251	15	Corn, field, oil-babyfood	0.005000	1.000	0.090	
15001260	15	Corn, pop	0.005000	1.000	1.000	
21000440	M	Beef, meat	0.000300	1.000	1.000	
21000441	M	Beef, meat-babyfood	0.000300	1.000	1.000	
21000450	M	Beef, meat, dried	0.000300	1.920	1.000	
21000460	M	Beef, meat byproducts	0.003000	1.000	1.000	
21000461	M	Beef, meat byproducts-babyfood	0.003000	1.000	1.000	
21000470	M	Beef, fat	0.003000	1.000	1.000	
21000471	M	Beef,fat-babyfood	0.003000	1.000	1.000	
21000480	M	Beef, kidney	0.001000	1.000	1.000	
21000490	M	Beef, liver	0.044000	1.000	1.000	
21000491	M	Beef, liver-babyfood	0.044000	1.000	1.000	
23001690	M	Goat, meat	0.000300	1.000	1.000	
23001700	M	Goat, meat byproducts	0.003000	1.000	1.000	
23001710	M	Goat, fat	0.003000	1.000	1.000	
23001720	M	Goat, kidney	0.001000	1.000	1.000	
23001730	M	Goat, liver	0.044000	1.000	1.000	
24001890	M	Horse, meat	0.000300	1.000	1.000	
25002900	M	Pork, meat	0.000010	1.000	1.000	
25002901	M	Pork, meat-babyfood	0.000010	1.000	1.000	
25002910	M	Pork, skin	0.000100	1.000	1.000	
25002920	M	Pork, meat byproducts	0.000100	1.000	1.000	
25002921	M	Pork, meat byproducts-babyfood	0.000100	1.000	1.000	
25002930	M	Pork, fat	0.000100	1.000	1.000	
25002931	M	Pork, fat-babyfood	0.000100	1.000	1.000	
25002940	M	Pork, kidney	0.000050	1.000	1.000	
25002950	M	Pork, liver	0.002000	1.000	1.000	
26003390	M	Sheep, meat	0.000300	1.000	1.000	
26003391	M	Sheep, meat-babyfood	0.000300	1.000	1.000	

26003400	M	Sheep, meat byproducts	0.003000	1.000	1.000
26003410	M	Sheep, fat	0.003000	1.000	1.000
26003411	M	Sheep, fat-babyfood	0.003000	1.000	1.000
26003420	M	Sheep, kidney	0.001000	1.000	1.000
26003430	M	Sheep, liver	0.044000	1.000	1.000
27002220	D	Milk, fat	0.010000	1.000	1.000
27002221	D	Milk, fat - baby food/infant for	0.010000	1.000	1.000
27012230	D	Milk, nonfat solids	0.000400	1.000	1.000
27012231	D	Milk, nonfat solids-baby food/in	0.000400	1.000	1.000
27022240	D	Milk, water	0.000400	1.000	1.000
27022241	D	Milk, water-babyfood/infant form	0.000400	1.000	1.000
27032251	D	Milk, sugar (lactose)-baby food/	0.000400	1.000	1.000
28002210	M	Meat, game	0.000300	1.000	1.000
29003120	M	Rabbit, meat	0.000300	1.000	1.000
40000930	P	Chicken, meat	0.000100	1.000	1.000
40000931	P	Chicken, meat-babyfood	0.000100	1.000	1.000
40000940	P	Chicken, liver	0.000600	1.000	1.000
40000950	P	Chicken, meat byproducts	0.002000	1.000	1.000
40000951	P	Chicken, meat byproducts-babyfoo	0.002000	1.000	1.000
40000960	P	Chicken, fat	0.002000	1.000	1.000
40000961	P	Chicken, fat-babyfood	0.002000	1.000	1.000
40000970	P	Chicken, skin	0.002000	1.000	1.000
40000971	P	Chicken, skin-babyfood	0.002000	1.000	1.000
50003820	P	Turkey, meat	0.000100	1.000	1.000
50003821	P	Turkey, meat-babyfood	0.000100	1.000	1.000
50003830	P	Turkey, liver	0.000600	1.000	1.000
50003831	P	Turkey, liver-babyfood	0.000600	1.000	1.000
50003840	P	Turkey, meat byproducts	0.002000	1.000	1.000
50003841	P	Turkey, meat byproducts-babyfood	0.002000	1.000	1.000
50003850	P	Turkey, fat	0.002000	1.000	1.000
50003851	P	Turkey, fat-babyfood	0.002000	1.000	1.000
50003860	P	Turkey, skin	0.002000	1.000	1.000
50003861	P	Turkey, skin-babyfood	0.002000	1.000	1.000
60003010	P	Poultry, other, meat	0.000100	1.000	1.000
60003020	P	Poultry, other, liver	0.000600	1.000	1.000
60003030	P	Poultry, other, meat byproducts	0.002000	1.000	1.000
60003040	P	Poultry, other, fat	0.002000	1.000	1.000
60003050	P	Poultry, other, skin	0.002000	1.000	1.000
70001450	P	Egg, whole	0.000500	1.000	1.000
70001451	P	Egg, whole-babyfood	0.000500	1.000	1.000
70001460	P	Egg, white	0.000500	1.000	1.000
70001461	P	Egg, white (solids)-babyfood	0.000500	1.000	1.000
70001470	P	Egg, yolk	0.000500	1.000	1.000
70001471	P	Egg, yolk-babyfood	0.000500	1.000	1.000
86010000	O	Water, direct, all sources	0.003290	1.000	1.000
86020000	O	Water, indirect, all sources	0.003290	1.000	1.000
95001750	O	Grape	0.041000	1.000	1.000
95001760	O	Grape, juice	0.002000	1.000	1.000
95001761	O	Grape, juice-babyfood	0.002000	1.000	1.000
95001770	O	Grape, leaves	0.041000	1.000	1.000
95001780	O	Grape, raisin	0.038000	1.000	1.000
95001790	O	Grape, wine and sherry	0.041000	1.000	1.000
95001950	O	Kiwifruit	0.041000	1.000	1.000
95002630	O	Peanut	0.016000	1.000	0.770
95002640	O	Peanut, butter	0.016000	1.890	0.770
95002650	O	Peanut, oil	0.054000	1.000	0.770
95003590	O	Strawberry	0.121000	1.000	1.000
95003591	O	Strawberry-babyfood	0.121000	1.000	1.000
95003600	O	Strawberry, juice	0.121000	1.000	1.000
95003601	O	Strawberry, juice-babyfood	0.121000	1.000	1.000

Attachment 9: Critical Commodity Analysis for the Cancer Analysis

```
U.S. Environmental Protection Agency                                 Ver. 2.00
DEEM-FCID Chronic analysis for TETRACONAZOLE                    (1994-98 data)
Residue file name: C:\Documents and Settings\tbloem\tetraconazole\corn and small fruit
vine and climbing subgroup except fuzzy kiwifruit\120603cancer.R98
                                                     Adjustment factor #2 used.
Analysis Date 04-13-2011/14:15:39     Residue file dated: 04-13-2011/14:06:02/8
Q* = 0.023
COMMENT 1: acute for females 13-50 only = 0.225 mg/kg/day; acute for remaining
populations = 0.50 mg/kg/day
===============================================================================
                 Critical Commodity Contribution Analysis for
                            U.S. Population (total)
                 Total Exposure =.0001106 mg/kg bw/day
            Crop groups with total exposure contribution > 3%
              Foods/Foodforms with exposure contribution > 3%
-------------------------------------------------------------------------------
Crop group                               -----------Exposure analysis----------
   Food                                     mg/kg   | % of Total| Lifetime Risk
      Foodform                           body wt/day|  Exposure |(Q*= .023)
--------------------------------------   -----------|-----------|--------------

Crop Group = (O)  Other
   Grape (95001750):
        FoodForm N/S                       0.0000040     3.63%        9.22E-08
   Grape, wine and sherry (95001790):
        FoodForm N/S                       0.0000053     4.75%        1.21E-07
   Strawberry (95003590):
        FoodForm N/S                       0.0000077     6.95%        1.77E-07
   Strawberry, juice (95003600):
        FoodForm N/S                       0.0000045     4.11%        1.04E-07
   Water, direct, all sources (86010000):
        FoodForm N/S                       0.0000399    36.11%        9.18E-07
   Water, indirect, all sources (86020000):
        FoodForm N/S                       0.0000294    26.61%        6.77E-07
--------------------------------------   -----------|-----------|--------------
  Total for crop group                     0.0000942    85.16%        2.17E-06

Crop Group = (D)  Dairy Products
  Total for crop group                     0.0000059     5.30%        1.35E-07

Crop Group = (6)  Legume Vegetables (Succulent or Dried)
   Soybean, oil (06003500):
        FoodForm N/S                       0.0000044     3.98%        1.01E-07
--------------------------------------   -----------|-----------|--------------
  Total for crop group                     0.0000046     4.20%        1.07E-07

Total for crop groups listed above:        0.0001047    94.66%        2.41E-06
-------------------------------------------------------------------------------
```